IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

Inventors:	Carsten Momma, Andreas Becker, Robert Schmiedl, and Bernd Heublien
Serial No.:	10/630,355
Filed:	July 30, 2003
For:	ENDOVASCULAR IMPLANT FOR THE INJECTION OF AN ACTIVE SUBSTANCE INTO THE MEDIA OF A BLOOD VESSEL
Art Unit:	3738
Examiner:	Brian E. Pellegrino

REPLY BRIEF

To: Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is an appeal under 37 C.F.R. §1.191 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the final rejection of claims 1, 3-15, and 26-29 in the above-identified patent application.

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The final page of **Section VII** of this reply brief bears the practitioner's signature.

III. STATUS OF CLAIMS

The status of the claims in this application is:

1. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are 18 pending claims in this application, numbered 1, 3-15, and 26-29.

In the Office Action of March 4, 2005, the Examiner stated that the application contained claims directed to three patentably distinct inventions: Invention I: Claims 1-29, classified in class 623, subclass 1.42; Invention II: Claims 30 and 31, classified in class 427, subclass 534; Invention III: claim 32, classified in class 430, subclass 281.1. The Examiner also indicated that the application contained claims directed to six patentably distinct species as follows:

Species A: Fig. 2	Species D: Fig. 5
Species B: Fig. 3	Species E: Fig. 6
Species C: Fig. 4	Species F: Fig. 7.

The Appellant elected Invention I, Species A with traverse. Claims 16-25 and 30-31 were withdrawn from consideration.

In the Amendment mailed March 29, 2006, the Appellant cancelled claims 2 and 30-32.

With regard to the claims on appeal, claims 1, 3-11, 14, 15 and 26-29 are generic, and claims 12 and 13 are directed to Species A (Fig. 2).

2. STATUS OF ALL OF THE CLAIMS

A. Claims canceled: 2, and 30-32.

B. Claims withdrawn from consideration but not canceled: 16-25.

C. Claims pending: Claims 1, 3-29.

D. Claims allowed: NONE.

E. Claims rejected: 1, 3-15, 26-29.

3. CLAIMS ON APPEAL

The claims on appeal are claims 1, 3-15, 26-29.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 3-12, and 26-29 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 6,254,632 to Wu et al.

2. Whether claims 14 and 15 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 6,254,632 to Wu et al. in view of U.S. Pat. No. 6,287,628 to Hossainy et al.

VII. ARGUMENTS

Currently, claims 1 and 3-29 are pending in the present application. Claims 16-25 have been withdrawn from consideration. Claims 1, 3-15 and 26-29 stand rejected.

In the Examiner's Answer of September 26, 2007, the Examiner submits that U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu") discloses a stent cover having a thickness of about 25 μm to 500 μm, and the microdevices 200 of Wu *may* protrude through the cover. From this the Examiner infers that it would have been obvious to one of ordinary skill in the art to have made the height of the microdevices fall between the claimed range of 100 to about 400 μm. However, taking the teachings of Wu in their entirety, the Examiner's inference is not reasonable.

It must be restated that the Examiner's inference of the microdevice height from the cover thickness is only one of several possible inferences. Additionally, Wu only provides for the delivery of therapeutic substances to the interior wall of a blood vessel, as evidenced by the recited lip height of the microdevices, 10-80 μm, and by the terminology used to describe these microdevices, i.e., "craters." Wu does not teach or suggest microcannulae that penetrate into the vessel wall to the media of the vessel. Wu only teaches that the "craters" "can be used to deliver therapeutic substances from the stent directly to the lumen wall…" (column 2, lines 60-62).

Furthermore, while the Examiner admits that Wu does not specifically disclose delivery of a therapeutic compound to the media, the Examiner maintains that "Wu discloses it is desirable to penetrate the vessel (col. 9, line19)." The Examiner's position in this regard is another inference, as seen by review of the cited portion of Wu. Column 9, line 19 provides that it is advantageous for the "protruding structures to anchor the covered stent to the lumen wall." Neither this section of Wu, nor any other, provides an explicit teaching that there is any

advantage that for a structure of a stent to actually penetrate a blood vessel wall. Wu speaks only of "anchoring," delivering therapeutic substances "directly to the lumen wall" (col. 2, lines 61-62), and "engag(ing) the lumen of the passageway when the stent is deployed, to help prevent the stent from slipping out of the treatment site" (col. 6, lines15-17). No teaching or suggestion can be found in Wu to penetrate the blood vessel wall to deliver therapeutic substances directly to the media layer of the blood vessel, as provided in the present application. Such a delivery allows for the use of lesser amounts of a therapeutic substance with concomitant reduction of production costs and potential side effects (see paragraph 0013).

The Examiner maintains that the Applicants have not provided any advantage or solution to a problem provided by a microcannulae length of 180-250 μm as recited in claims 3 and 4. This is incorrect. Paragraph 0036 of the specification clearly provides that microcannulae of a length of 150 -300 μm are of particular usefulness in intracardial use and that a length of 180-250 μm are effective in assuming the desired position in greater than 90 percent of cases.

Finally, the Examiner maintains that Wu "indeed discloses that the active substance is intended to be released into the media when the microcannula secure the stent to the wall, se col. 6, lines 21-26." Again, this is an inference on the part of the Examiner, based on the present disclosure. As with other sections of Wu cited by the Examiner, this section of Wu cited by the Examiner is directed to delivery of the therapeutic substances "directly to the tissue of the lumen wall." As explained previously, Wu's reference to the "lumen wall" indicates that the therapeutic substance is only delivered to the endothelium of the blood vessel, because a "lumen" is actually an inner open space or cavity, in this case, of the blood vessel. Therefore, by using this terminology, Wu can only mean that the craters 200 contact ("engage") the wall of the blood vessel at its inner surface. Wu does not teach or suggest structures that penetrate into the

vessel past the endothelium, the basal lamina, and the inner elastic membrane and allow delivery of such substances directly into the media.

Therefore, the scope and content of the prior art does not teach or suggest the claimed invention and all the pending claims are allowable for at least the following reasons:

1. Wu does not teach or suggest all the elements of claim 1, from which the remaining pending claims depend.
2. There is no motivation to modify the microstructures of Wu to provide microcannulae that deliver an active substance to the media of a blood vessel.
3. There is no reasonable expectation of success in the microstructures of Wu to provide microcannulae that deliver an active substance to the media of a blood vessel

In accordance with the foregoing, the Applicants respectfully request reversal of the Examiner and allowance of all pending claims.

Respectfully submitted,

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